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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,455	02/09/2001	Tarun K. Dhar	056859/0115	6699

22428 7590 07/19/2004

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

09/779,455

Applicant(s)

DHAR ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,12-20 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,12-20 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/2004 has been entered.
2. Claims 1-6, 8-10, 12-20 and 44 are pending.
3. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 1-6, 8-10, 12-20 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not have support in the specification as filed. Claim 1 is further confusing because the recitation of "the upper reaction membrane" and "the lower bottom support layer" lacks antecedent basis.

Claim 2 is confusing because it recites that the liquid impervious body is attached directly to the reaction membrane and the support layer; however, claim 1 from which it depends recites that the absorbent material is also in contact with the reaction membrane and the support layer, therefore, it is unclear where and how the absorbent material and the liquid impervious body are disposed.

Art Unit: 1641

Claim 20 is vague because it is unclear where the additional absorbent bodies are placed in the device.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6, 8-10, 12-20 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims, as amended, are directed toward a device comprising a reaction membrane having antigens or antibody spotted thereon positioned on top of an absorbent material and is in turn, fixed to a support layer. The device may further include a strip of liquid impervious body placed between the reaction membrane and the support layer. Such a device does not have support in the specification as originally filed.

The specification as pages 13-15 discloses a device comprising a reaction membrane having antigens or antibody spotted thereon and is attached to a solid support layer. The device may further include a strip of liquid impervious body placed between the reaction membrane and the support layer. Absorbent bodies are recited as not fitted together with the reaction membrane and are provided separately with the analyte device. Furthermore, the

Art Unit: 1641

specification recites that a single analytical device contains more than one disposable absorbent body.

The specification teaches that the absorbent bodies are assembled to the device during an assay. Specifically, page 15 discloses that the absorbent body is not fixed permanently with the device but is assembled during the assay and that the construction format of the device allows the discarding of used absorbent body with new one thereby permitting the application of signal amplification reagents for improving sensitivity of the assay.

Nowhere in the specification is there a disclosure of a final product comprising the device as claimed in claim 1.

Applicant is required to cancel the new matter in response to this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-6, 8-10, 12-20 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 5,885,526) in view of Bhattacharya et al (Journal of Immunological Methods. 227:31-39. 1999).

Chu discloses an analytical device made by using readily available materials. Referring to FIG. 1, the analytical device comprises a liquid-impervious top support layer (10) that defines a rim (12) around an open port (11). A porous reaction membrane (13) is located beneath the top

Art Unit: 1641

support layer such that, after the device is assembled, a sample receiving well is defined by the exposed upper surface (14) of the reaction membrane and the rim (12) around the open port (11). An absorbent body (15) is located beneath the reaction membrane. The device may further comprise a liquid-impervious bottom support layer (16) having an upper surface in contact with the lower surface of the absorbent body. See column 3, lines 33-45. Multiple sample receiving wells can be formed as depicted in Figures 8-10 to test for multiple analytes in one sample, or a single reaction membrane, with multiple receptor and control areas can be used. See column 4, lines 40-64. Chu teaches an intermediate layer comprising a liquid impervious septum between the reaction membrane and the support layer. See column 6, line 65 through column 7, line 2. Chu teaches that more than one layers of absorbent body may be used. See column 7, lines 7-16. Chu also teaches blocking unused sites with conventional blocking agents. See column 10, lines 39-51.

Chu differs from the instant invention in failing to teach the use of electron-rich blocking proteins.

Bhattacharya, however, discloses the use of electron-rich blocking proteins such as p-hydroxy-phenylpropionic acid-casein conjugates and p-hydroxy-phenylpropionic acid-gelatin conjugates as blocking agents. Bhattacharya teaches that such blocking agents provide the advantage of an increase in sensitivity and increased the detection limits in ELISA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the blocking agents taught by Chu with those of Bhattacharya for the advantages of an increase in assay sensitivity as well as an increase in the detection limits in ELISA.

Art Unit: 1641

Response to Arguments

7. Applicant's arguments and Declaration filed on 2/26/2004 have been considered but are moot in view of the new ground(s) of rejection.

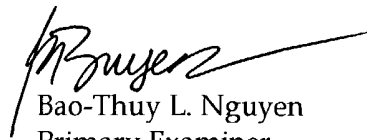
Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641